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APPLICATION FOR EXEMPTION

Re: Request for Exemption from 21 CFR 801.437 (d) and (e), Natural Rubber-Containing Medical Devices; User Labeling. Docket Number 96N-0119.

Subject: Cintas First Aid & Safety Products Containing Natural Rubber

Date: November 30, 2000

Summary

This is a request for exemption from 21 CFR 801.437 (d) and (e) which requires labeling of medical devices to indicate the presence of natural rubber in its various forms, either Dry Natural Rubber or Natural Rubber Latex. Due to differences in the manufacturing processes of our suppliers, we are requesting an exemption which allows the use of the phrase "may contain" on the *outer container only* of our fabric adhesive bandages. All labeling of the immediate container would continue to comply fully with the requirements of 21 CFR 801.437 (d) and (e).

Overview of Cintas First Aid & Safety

Cintas First Aid & Safety, a subsidiary of the Cintas Corporation of Cincinnati, Ohio, is a wholesale distributor of first aid and safety products. These products are distributed to independent and company-owned distributors who subsequently provide van-delivered service to our customers in the workplace. This service generally consists of the restocking of on-site first aid cabinets.

Description of Products

The products for which this exemption request is being submitted consist of various sizes and types of fabric adhesive bandages which may contain natural rubber in their adhesive. Examples include elastic strips, elastic fingertip bandages, elastic knuckle bandages, and elastic patches.

Manufacturing and Distribution Process

Cintas First Aid & Safety receives finished bandages in bulk form, and subsequently repackages them into various sized dispenser boxes suitable for use by the end user. These products are purchased by first aid distributors who provide van-delivered service to their industrial customers.

Justification for Exemption

We have multiple vendors who provide us bulk adhesive bandages which we then repackage into privately labeled boxes. Some of our vendors have switched to a latex-free adhesive and therefore do not require any latex warning for their product. Our other vendors utilize a dry natural rubber process and provide their bandages with an immediate container (paper wrapper) which bears the complete warning required by 21 CFR 801.437 (d) and (e). We considered several alternative solutions to this problem. Each of these alternatives is discussed below.

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Alternative 1: Require a consistent adhesive formulation from all vendors

- Due to the proprietary adhesive formulations of our vendors, it is impractical to require our vendors to standardize on a particular adhesive formula.
- Adhesive formulations vary with the design of the coating equipment. Due to differences in our vendor's equipment, we are not able to specify a single adhesive formulation from all manufacturers.

Alternative 2: Purchase from a single supplier

- It is impractical for us to rely on a single vendor for these products, since maintaining multiple vendors is a requirement for reliable distribution.
- If supply problems occurred without an alternate vendor to rely on, we would be unable to provide adhesive bandages to thousands of consumers.

Alternative 3: Maintain separate inventories for latex and non-latex products

- Maintaining a stock of 2 different boxes (one with the latex warning and the other without) would complicate our assembly process and result in a significant increase in our inventory of both bulk and finished goods, along with a corresponding increase in cost to the consumer.
- The assembly process for placing different bandage formulations into boxes with different labeling (with and without latex warnings) could result in a high chance of assembly errors. These products are visually almost identical and production errors could easily result as the bandages are placed into their boxes.
- Since the ultimate goal is to protect the consumer, an alternative that could actually increase the chance of labeling errors would be inappropriate.

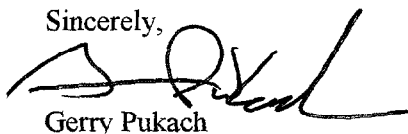
Exemption Request

We request an exemption to 21 CFR 801.437 (d) and (e) that will allow us to use the following statements on the *outer* container as appropriate:

1. "Caution: This Product May Contain Natural Rubber Latex Which May Cause Allergic Reactions."
2. "This Product May Contain Dry Natural Rubber."

Labeling of the *immediate* container (paper wrapper) would continue to comply fully with all requirements of 21 CFR 801.437 (d) and (e). The result would be that individuals who are latex sensitive would be alerted to the possibility that latex may be present when they read the outer container labeling. As they proceed to the immediate container, the labeling would definitively confirm the presence of latex if it exists in the product. If latex sensitivity is a problem, they would have the opportunity to select an alternative to our fabric bandage line, such as a plastic bandage which does not contain latex.

Sincerely,



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